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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,492	03/21/2001	Mark A. Labow	4-31360A/USN	2101
1095	7590	12/03/2003	EXAMINER	
THOMAS HOXIE NOVARTIS, CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,492	LABOW ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed Aug. 20, 2003 is acknowledged. Claim 6 was canceled. Claims 7-17 were added.

Claims 1-5 and 7-17 are pending.

Claims 3-5, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1, 2 and 7-17 are examined on the merits.

Claim Rejections Withdrawn:

2. The rejection of claims 1, 2 and 6 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment.
3. The rejection of claims 1, 2 and 6 under 35 U.S.C. 103(a) as being unpatentable over either Band (supra) or Vogelstein (supra) in view of Coghlan (Coghlan, et al., Analytical Biochemistry, 149: 1-28, 1985) is withdrawn in view of the cancellation of claim 6.
4. The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, for lack of enablement commensurate with the scope of the claims is withdrawn in view of the amendment to claims 1 and 2.

Claim Rejections Maintained:

5. The rejection of claims 1 and 2 under 35 U.S.C. 102(e) as being anticipated by either Band (U.S. Patent 6,153,387; issued 11/28/2000; effective filing date 6/6/1995) or Vogelstein et al (U.S. Patent 5,527,676; issued 6/18/1996; effective filing date 8/17/1992) is maintained.

Claim 1, as currently amended, reads on a method for detection of a polynucleotide comprising providing a probe that hybridizes to a nucleic acid sequence given by SEQ ID NO: 1 or a fragment thereof. The fragment may be of any size. The phrase “given by” is interpreted to have the same scope as “comprising”. Therefore the claims read on detecting a polynucleotide that has only one nucleotide in common with SEQ ID NO: 1.

Band discloses a methods for the detection of breast cancer in breast tissue, comprising contacting a biological sample that may be breast tissue with a probe that would comprise a fragment of SEQ ID NO:1, where a decrease in hybridization indicates that the patient has a malignancy (see claims 11 and 13) Band teaches a probe that is a NES1 cDNA fragment (col. 17, lines 42-45; and col. 10, lines 1-11) that is at least 10 nucleotides in length. Thus, Band discloses and claims the claimed methods.

Vogelstein discloses methods for the detection of breast cancer in breast tissue, comprising contacting a biological sample that may be breast tissue with a probe for the purpose of detecting the loss of p53 nucleic acids, wherein a decrease in signal indicates the presence of breast cancer (see claims 1, 4, 5, and 19).

New Grounds of Rejection:

The following rejections were necessitated by the amendment.

6. Claims 1, 2, and 12-15 are rejected under 35 U.S.C. 102(e) as being rejected by Papsidero (U.S. 6,306,653; issued Oct. 23, 2001; filing date Sep. 3, 1998).

This rejection was previously withdrawn for claims 1 and 2. However, the scope of the amended claims and new claims 12-15, places the claims within the scope of the invention of Papsidero.

Papsidero teaches a nucleic acid sequence (SEQ ID NO: 11) that comprises a fragment of SEQ ID NO: 1, where the fragment is at least about 10 nucleotides (see enclosed alignment). Papsidero teaches the use of probes, such as SEQ ID NO: 11, or its complement, and teaches methods of using these polynucleotides in methods of polynucleotide detection (col. 19, line 9 -- col. 20, line 41). Thus, Papsidero teaches methods that are the same as that claimed.

7. Claims 1, 2, and 7-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 12 and 16 are indefinite (and therefore, the dependent claims thereof are indefinite) because of the recitation "stringent conditions" or "highly stringent conditions". The specification does not describe either "stringent" conditions or "highly stringent" conditions in such a way as to define these terms, or to differentiate them from each other, or each of them from non-stringent conditions. The specification teaches that "[g]enerally, highly stringent

conditions are selected to be about 5°C lower than the thermal melting point for the specific sequence at a defined ionic strength and pH" (page 4, 2nd para.). This teaching does not suffice to describe the full breadth of what is encompassed by "highly" stringent conditions, and fails to describe how "highly stringent" conditions are differentiated from "stringent" conditions, or non-stringent conditions. Although, the specification provides one algorithm for determining "highly stringent" conditions, the specification fails to describe circumstances under which any other algorithm may be used, and fails to provide any algorithm for determining "stringent" conditions. Therefore, the specification fails to describe the metes and bounds of what would be considered "highly stringent" or "stringent" hybridization conditions.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
November 25, 2003

